Innovative Egg Products
M.G. WALDBAUM
A MICHAEL FOODS COMPANY

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FSIS RECEIVED HEARING CLERK
99 SEP 13 AM 9:35

September 9, 1999

USDA/FSIS Hearing Clerk
Room 102 Cotton Annex Building
300 12th Street SW
Washington, DC 20250-3700

Re: USDA, FSIS Docket No. 98-045N2
HHS, FDA Docket No. 98N-1230

Dear Sirs:

Michael Foods, Inc. submits the following comments and information on issues raised concerning "Egg Safety Action Plan; Public Meeting" published in the *Federal Register* (Vol. 64, No. 156, August 13, 1999, pp. 44195-44196) as well as issues raised during the Public Meeting held on August 26, 1999.

In the Federal Register Notice, the Overarching Goal of the Egg Safety Action Plan was: *"To protect public health by significantly reducing the number of foodborne illnesses associated with SE in shell eggs and egg products through science-based and coordinated regulation, inspection, enforcement, research, and education programs."* At the August 26 meeting, a revised draft of the Overarching Goal was restated: *"To eliminate the incidence of SE illnesses associated with the consumption of shell eggs and egg products. The Egg Safety Action Plan has set an interim goal of a 50% reduction in SE illnesses by 2005."*

The restated Overarching Goal is an admirable goal that includes a specific illness reduction target. To date, most of the emphasis for addressing the public health impact of egg related SE has been directed to on-farm production practices. Improved production practices, uniform quality management programs, temperature control during distribution of shell eggs, prohibitions against repackaging of shell eggs, and consumer education all have value as risk reduction strategies. However, no single or combined approach provides the margin of safety achieved by pasteurization of shell eggs or egg products. To achieve the 50% illness reduction goal, we believe that there must be greater utilization of pasteurized eggs, especially by the growing at-risk segment of the population.

The following comments address the four Goals presented in the Federal Register Notice:

Goal 1: Promote implementation of existing technologies...

(a) Over the last 30 years, the U.S. egg products industry has responded to consumer demands for high-quality, *Salmonella*-free, and convenient egg products with the development of a wide range of further processed egg products. These real egg products include various liquid, frozen, dried and precooked items containing whole egg, yolk, albumen or blends. To date, not a single case or outbreak of salmonellosis has ever been traced to the consumption of a pasteurized egg product. We would like to emphasize that the term "egg product" specifically refers to eggs that have been pasteurized to reduce *Salmonella* food safety risks, as mandated under the Egg Products Inspection Act of 1970. As such, it is important to note that the USDA and FDA's use of the term "egg product" is misleading in the following statement from the August 13, 1999 *Federal Register* announcement:

> *"Overarching goal: to protect public health by significantly reducing the number of foodborne illnesses associated with SE in shell eggs and* ***egg products*** *through science-based coordinated regulation...."* (p. 44196).

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In regard to pasteurized egg products, it is unreasonable to expect to significantly reduce a level of illness that has not been shown to exist. As an alternative, we recommend the use of the term "egg-containing foods" to describe complex foods which contain unpasteurized egg components.

(b) Due to the clear association between unpasteurized shell eggs and the transmission of SE foodborne illness, we recommend that the U.S. Public Health Service and the FDA **mandate** adoption, by all U.S. states and territories, of all sections of the model Food Code that pertain to the safe storage, handling and cooking of unpasteurized eggs in the retail and foodservice sectors. The Food Code also stipulates that pasteurized shell eggs or egg products (liquid, frozen, dried, or precooked eggs) be substituted for ordinary shell eggs in all foodservice recipes served to the highly susceptible segment of the population which includes the elderly, pregnant women, preschool children and a range of persons with impaired immune function (section 3-801.11 B). It is difficult to envision a situation in which a restaurant or other foodservice operation could be certain that it was not serving egg-containing foods to a number of persons belonging to this "higher-risk" group. For foodservice kitchens serving the general population, the model Food Code stipulates that pasteurized eggs or egg products be substituted in all uncooked or lightly-cooked delicatessen and menu items that typically contain raw eggs (e.g., sunny-side-up fried eggs, undercooked scrambled eggs, uncooked sauces, protein shakes, etc.), unless the consumer is informed in writing of the increased risk (section 3-302.13). Mandating these sensible egg safety practices nationwide would go a long way toward achieving meaningful reductions in the risks to public health posed by unpasteurized and undercooked eggs served in the foodservice and retail sectors.

(c) The USDA should prohibit the re-washing and re-packaging of "store-return" shell eggs intended for retail consumer or foodservice markets, or for use as breaking stock. These eggs are subject to extensive handling by consumers and retail employees, lengthy shipping cycles, and potentially, various degrees of elevated temperature abuse. This prohibition should be given the force of law and should apply to **all** shell egg producers, not merely the 21% of the industry currently operating under the voluntary USDA grading program. The only recommended alternative for salvaging shell eggs returned from commercial channels should be the production of "inedible" egg material for use in animal feeds.

(d) It is the experience of M.G. Waldbaum Co. that an egg production quality assurance control program is effective in minimizing SE infections of flocks and allows early identification of infected flocks. The program includes the seven elements summarized by the Government Accounting Office in its July 1999 Food Safety report (p. 8). The program significantly reduces risk of infection by SE, but is not totally effective in preventing *Salmonella enteritidis* infections of flocks. The annual costs to operate a program, including microbiological testing, are in the range of $20 to $30 per thousand hens and require trained staff. If vaccination is included in a control program it adds approximately $100 per thousand hens. Those costs are the incremental costs over the normal house and flock management costs required to maintain healthy and productive egg laying flocks.

We recommend that a uniform model risk reduction program be established for the entire U.S. egg production industry. Since SE control programs are designed to address public health issues, it would not be good policy to exempt small producers from conforming with any future regulations requiring the implementation of quality assurance risk reduction programs. To insure uniform application of any future nation-wide control program, FDA, USDA, and state regulatory bodies should work cooperatively to provide guidance to small producers to develop and implement standardized control programs. Model control programs should be devised and made available to firms that request assistance in adopting best practices that would assist their implementation of risk reduction programs. At some point all entities participating in the production, distribution and sales of shell eggs must accept that uniformly practiced risk management programs are a part of the cost of doing business.

Goal 2: Examine Alternative Regulatory Structures...

We support and encourage the transition to a science-based approach to food safety assurance and regulatory oversight in the U.S. further processed egg industry. While Sanitation Standard Operating Procedures (SSOPs) are an essential prerequisite program, the Hazard Analysis Critical Control Point (HACCP) system represents the cornerstone of this approach. The implementation of HACCP requirements for the entire U.S. egg processing industry would be consistent with the July 1996 Final Rule issued by the USDA FSIS mandating that HACCP be implemented as the system of process control in all inspected meat and poultry plants. Under a fully-developed HACCP system, the role of the USDA FSIS would transition to that of providing *oversight* to the processing plant rather than the continuous, primarily visual inspection system currently in place. This transition would be consistent with the following recommendations of the National Research Council's Committee to Ensure Safe Food from Production to Consumption:

- "Eliminate continuous inspection system for meat and poultry and replace with a science-based approach which is capable of detecting hazards of concern;" and
- "Mandate a single set of science-based inspection regulations for all foods."

Reference: Institute of Medicine, National Research Council. 1998. Conclusions and Recommendations, chap. 6. *In* Ensuring Safe Food: From Production to Consumption. National Academy Press, Washington, DC.

While the U.S. further processed (pasteurized) egg industry has an outstanding record of delivering safe egg products to the consuming public*, the transition of the industry to a HACCP-based approach, with an appropriate level of regulatory oversight, would provide the maximum level of food safety assurance and would represent the best use of available USDA FSIS resources. The development of model HACCP-based programs for egg products processing is such a significant task that we strongly encourage the involvement of all relevant stakeholders in the process of developing the proposed HACCP models, through a series of public meetings and information exchanges.

*i.e., no cases or outbreaks of salmonellosis have been traced to a pasteurized egg product source.

Goal 3: To change, through education, unsafe egg handling practices by producers, distributors, retailers and consumers...

The Michael Foods Egg Division supports the FDA's proposed rule that would require "Safe Handling Instructions" on all consumer and foodservice packages of unpasteurized shell eggs. However, we oppose the use of the first sentence in the proposed label. The language proposed by FDA on July 6th (i.e., *"Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems."*) seems unnecessarily harsh and alarmist. The second statement regarding proper egg refrigeration and thorough cooking would serve a useful purpose in educating consumers regarding proper egg handling practices. The key point to bear in mind is that the objective of developing the consumer egg safety statement is **to effectively influence and modify consumer behavior.** We would also support the addition of the following sentence, or similar language:

> *"Use pasteurized egg products or pasteurized intact shell eggs for any recipe that does not require that the dish be cooked thoroughly."*

The latter statement would serve the purpose of alerting retail customers and foodservice operators that there are safe, pasteurized alternatives to conventional unpasteurized shell eggs.

Furthermore, we recommend that the Agencies establish and mandate a uniform expiration date labeling system for retail shell eggs with a defined base for establishing the "use by" date. Uniform expiration dating, based on the date of lay, would provide for better lot control, enhance egg safety risk reduction programs, and provide a more accurate and understandable label for consumers.

Goal 4: To identify and develop new technologies to ensure safer shell eggs and egg products through research.

During the Egg Safety Public Meeting on August 26, 1999, the idea was put forth that government-sponsored research on in-shell egg pasteurization should be funded at the federal level. Michael Foods contends that both the science behind its in-shell egg pasteurization process and scale-up and engineering aspects of the process are now well understood and have been reduced to practice.

Michael Foods has been producing and selling Pasteurized Shell Eggs for more than three years. The eggs are pasteurized using a proprietary gentle heating process developed by Michael Foods. No chemicals, irradiation or additives are used to pasteurize the product. Use of this In-shell Pasteurized product assures food safety even in recipes in which the eggs are raw, lightly cooked, or undercooked. The retail distribution has been primarily restricted to the state of Minnesota. In that market, they represent about 4% of the shell egg sales. The pasteurized shell eggs are being sold at a constant year-round price of $1.89 per dozen in contrast to the normal retail pricing patterns that may reflect general market conditions or sales promotion pricing for eggs. The market share for pasteurized shell eggs in that market is typical of market shares held by other specialty eggs, several of which are sold at a higher retail price.

Pasteurized shell eggs sold at the retail level are packaged in a clear carton that is sealed with a tamper-evident strip. At the volumes currently used, this package is relatively expensive compared to typical retail egg cartons, but provides good physical protection to the contents and allows the customer to visually inspect the eggs without opening the package. The tamper evident strip provides security to assure the customer that the eggs have not been exposed to handling by others, minimizes post-process exposure and possible post-process contamination of the eggs. An alternative, less costly packaging approach has been developed for the foodservice sector. Each egg has also been coated with a food grade wax to form a protective coating on the shell to minimize potential for post process infection through open pores in the shell. A stylized "P" is printed on each egg to allow customers to identify the eggs once they open the carton at the point of use and consumption. These eggshell labeling and packaging procedures are consistent with the post-process protection safeguards recommended by the FDA and USDA in the Sept. 24, 1997 *Federal Register* notice "Pasteurized Shell Eggs (Pasteurized In-shell Eggs)," Docket No. PY-97-008.

Over three years of experience with the processing and commercial sale of In-shell Pasteurized Eggs has allowed Michael Foods to demonstrate that the process can be successfully accomplished and carried out in a cost-effective manner. Certainly, the installation of equipment to pasteurize eggs in the shell represents an added cost that must be accounted for the in the marketing and sale of this safe, value-added shell egg product. Similarly, at the time that the Grade A Pasteurized Milk Ordinance went into effect (1978) as a means to improve the safety and quality of the milk supply, significant investments in equipment, along with changes in processing regimes, labeling, etc. were also required of the dairy industry. The overall safety record of pasteurized milk *vs.* raw milk is one of the great food safety success stories of the 20th century.

The scientific research on which the Michael Foods In-shell Pasteurization process is based was conducted at two leading research Universities and published in a peer-reviewed international microbiology journal (*J. Appl. Microbiol.* 83:438-444). The critical question answered during the course of this research was: Can the time-honored pasteurization principles that allow production of safe, *Salmonella*-free further-processed liquid, frozen and dried eggs be applied to high-quality intact eggs? That question was successfully answered in the affirmative using a set of rigorous experimental designs involving the inactivation of a variety of egg-associated serotypes of *Salmonella*. In recognition of the scientific credibility and value of this published research in improving egg safety, the authors were awarded the 1998 Research Award presented by the American Egg Board. Subsequent to this University research, the Michael Foods In-shell Pasteurization process was refined and scaled-up to achieve a consistent 5-log reduction of *Salmonella* species in the center of each egg, while minimizing any potential negative impact on the flavor, appearance, consistency and functional performance of the

eggs. Egg cooking/performance testing by an independent consultant has verified that Michael Foods Pasteurized shell eggs are virtually identical to ordinary shell eggs in terms of recipe preparation, appearance, taste, texture and overall quality. Corporate licensing agreements for use of the proprietary Michael Foods technology are currently available to interested egg processors at reasonable fees. On April 1, 1999, the efficacy of the In-shell Pasteurization process developed by Michael Foods was officially recognized in a letter from the FDA Center for Food Safety and Applied Nutrition. In accordance with Docket No. PY-97-008, this officially qualifies Michael Foods to use the term "pasteurized" in conjunction with its pasteurized shell egg labels. Additional engineering research has led to the development of an improved second-generation In-shell Pasteurization process using a new, and even more commercially attractive approach. The efficacy of this novel approach has again been scientifically validated by conducting rigorous inoculated challenge experiments at a leading University.

The Michael Foods In-shell Pasteurization process is a scientifically credible, commercially proven and cost-effective means to provide consumers with significantly safer intact shell eggs. We encourage the USDA and FDA to recognize that although there are a range of "farm-to-table" approaches which may marginally reduce SE safety risks related to shell eggs, no single approach will be as consistently and universally effective as the **pasteurization** of intact shell eggs and liquid egg. Pasteurization is a proven, genuine Critical Control Point ("kill step") within the HACCP system for assuring food safety, and is therefore consistent with both the emerging regulatory direction of the FDA and USDA, and the federal Food Safety Initiative. We encourage all relevant regulatory agencies, including state Health Departments, to promote the increased availability and usage of a full range of pasteurized egg products, including In-shell Pasteurized eggs, particularly for the growing at-risk segment of the U.S. population. As stated previously, the most scientifically-based means of improving egg safety and protecting public health at the retail foodservice level is to mandate adoption, by all U.S. states and territories, of all sections of the 1999 model Food Code that pertain to the safety of shell eggs and egg-containing foods.

Lastly, we would like to highlight the following topics that are worthy of publicly supported research:

1. An objective assessment of the impact, if any, of forced molting on the susceptibility of egg-laying flocks to colonization by *Salmonella enteritidis (SE)*.
2. An evaluation, throughout the laying cycle, of the maintenance of immunity (i.e., appropriate antibody titers) and protection from *SE* colonization of hens which have been vaccinated using commercially available vaccines.
3. An assessment of the efficacy of competitive exclusion (probiotic) approaches designed to protect laying flocks from colonization by Salmonellae throughout the laying cycle (including molting).

It should be noted that the value of all three proposed research projects would be enhanced by conducting the studies using hens maintained in commercial production environments.

We respectfully submit these comments for your consideration and appreciate the opportunity to comment on the egg Safety Action Plan.

Sincerely yours,

Hershell Ball, Jr.

Hershell Ball, Jr., Ph.D.
Vice President
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CROSS FILE SHEET

File Number: 98N-1230/C 819

See File Number: 97P-0197/ C 820

96P-0418/ C 819